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IN-BLOOD COMPONENT CONCENTRATION MEASUREMENT DEVICE

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Claim

A type of in-blood component concentration measurement device characterized by the fact that the in-blood component concentration measurement device comprises the following parts: a main body of the measurement device, a lancet mounted in an appropriate position of the main body of the measurement device in a quick connect/disconnect manner, a cap body for the lancet to fit on the aforementioned main body of the measurement device in a quick connect/disconnect manner and covering the lancet, and an enzyme electrode which is set inside the aforementioned cap body for the lancet, and which has its connecting terminal extending to the outside and connected to the connector of the aforementioned main body of measurement device.

Detailed explanation of the invention

Industrial application field

This invention pertains to a measurement device for measuring the concentration of components in blood by means of an enzyme electrode. More specifically, this invention pertains to a type of in-blood component concentration measurement device which allows measurement of the concentration of the biochemical substances in blood right after collection of the blood sample.

Prior art

As the conventional in-blood component concentration measurement devices using enzyme electrodes, there are the so-called discrete system and flow system of the clinical examination devices. These devices can perform almost automatic operation for dilution of samples, measurement, calibration of device, and cleaning. However, the devices are large in size and are expensive with high running costs. Also, no extended length of time is needed in measurement, and large amounts of samples and buffer solutions are needed, but also skillful workers are needed to operate them, and service and control of the devices are complicated.

In the recent years, the in-blood component concentration measurement device shown in Figure 6 that can perform a measurement in a simple manner has been proposed. In this in-blood component concentration measurement device, display unit (52) and operation unit (53) are set in case body (51). Also, cartridge (54) is set in a quick connecting/disconnect manner. On said cartridge (54), immobilized enzyme film (55) is supported. As cartridge (54) is installed on case body (51), enzyme film (55) is bonded on the substrate electrode (not shown in the figure) exposed below said cartridge (54) to form an enzyme electrode.

In the measurement of the in-blood component concentration, a piercing needle known as a lancet (not shown in the figure) is used to prick a finger tip to get a droplet of the vein blood, and blood droplet (56) is allowed to fall onto enzyme film (55). Then, after the concentration is measured by the enzyme electrode, blood droplet (56) is wiped up. In this case, a droplet of a reference solution (calibrating solution) and a droplet of a buffer solution (cleaning solution) were also applied and wiped up.

Problems to be solved by the invention

The aforementioned conventional in-blood component concentration measurement device has a small size and a low cost. Also, it does not need maintenance. However, it does have the following problems.

① One has to prepare both the main body of the measurement device and the lancet as a separate body from the main body of measurement device. Also, after the in-blood component concentration measurement device is set in the measurable state, one has to make use of the lancet to collect the blood sample. The operation procedure is complicated.

② After collection of the blood sample by means of the lancet, when the finger is moved to the main body of measurement device, one has to prevent the blood from falling off. Also, as one droplet of blood has to fall on the portion of the enzyme film, care should be taken in handling.

③ The measurement value depends on the position of instilling of the blood sample onto the enzyme film and the falling speed of the blood. Also, the amount of the blood instilled should

be sufficient to fill up the entire region of the enzyme film, and care should be taken in the measurement.

④ In order to clean after measurement or calibration, one has to repeatedly perform the operation of instilling of the cleaning buffer solution on the enzyme film and then wiping it off. This makes the operation complicated and time consuming. Also, if the surface of the substrate electrode is directly touched while wiping off, the surface of the substrate electrode may be scratched and damaged. On the other hand, if wiping is carried out insufficiently, the liquid droplet would be left on the enzyme film and will influence the next round of measurement adversely. The so-called carry-over degrades the measurement precision.

⑤ As the substrate electrode and the enzyme film are separated from each other, the degree of adhesion between the substrate electrode and enzyme film is reflected in the measurement result, and this may lead to deterioration of the measurement precision. When the enzyme film is mounted on the substrate electrode, in order to realize a high adhesion degree, damage to the enzyme film frequently takes place. Also, for the surface of the substrate electrode, in order to realize a high adhesion with the enzyme film, it has to be processed to a convex shape, and the manufacturing cost is thus very high.

⑥ When the enzyme film is exchanged, one has to perform a complicated operation such as instilling the solution on the surface of the substrate electrode. Also, the amount of the instilled solution affects the measurement result. Besides, for a while after the exchange, the electrode output is not stable, and a long time is needed for it to become possible to perform the measurement.

⑦ When the substrate electrode is broken, the substrate electrode becomes integrated with the case body, thus making it impossible to exchange it.

These are disadvantages.

The purpose of this invention is to solve the aforementioned problems of the conventional technology by providing an in-blood component concentration measurement device characterized by the fact that the main body of the measurement device and the lancet (piercing needle) are integrated, and an enzyme electrode is set inside the cap body for the lancet, so that the measurement preparation can be simply made, handling is easy, and the measurement precision is high.

Means to solve the problems and function

In order to realize the aforementioned purpose, this invention provides a type of in-blood component concentration measurement device characterized by the fact that the in-blood component concentration measurement device comprises the following parts: a main body of the measurement device, a lancet mounted in an appropriate position of the main body of the

measurement device in a quick connect/disconnect manner, a cap body for the lancet to fit on the aforementioned main body of measurement device in a quick connect/disconnect manner and covering the lancet, and an enzyme electrode which is set inside the aforementioned cap body for the lancet, and which has its connecting terminal extending to the outside and connected to the connector of the aforementioned main body of the measurement device.

In the in-blood component concentration measurement device with the aforementioned configuration, a lancet is set protruding from the tip of the cylindrical rod shaped main body of measurement device. On the other hand, the cap body for the lancet is a cylindrical case that also becomes the tip of a micropipette. On the inner surface near the tip of the case (cap body), a film-shaped enzyme electrode having a connecting end is set. The connecting end of the enzyme electrode is inserted into the connector of the main body of the measurement device. The lancet can be disposed protruding out from the tip side of the cap body for the lancet. Consequently, when a finger is pricked by the protruding lancet, the blood from the tip of the finger is attached on the enzyme electrode on the inner surface of the cap body for the lancet, and the in-blood component concentration is measured. That is, in this measurement device, the lancet and the enzyme electrode are integrated with the main body of the measurement device. As a result, the preparation for measuring becomes simpler, and a measurement can be made easily by performing the operation of a micropipette. Also, as there is no need to move the finger with the blood droplet on it, the collected blood sample can be used in the measurement for sure. In addition, by operating the plunger of the main body of measurement device, the reference solution and the cleaning buffer solution can be fed and exhausted. Consequently, in the wiping operation, the enzyme electrode is not touched, and damaging of the enzyme film and scratching of the substrate electrode can be prevented. Also, exchange of the enzyme electrode can be carried out simply by connecting/disconnecting the cap body for the lancet.

Application examples

Figure 1 is an oblique view illustrating an application example of the in-blood component concentration measurement device in this invention.

The in-blood component concentration measurement device comprises the following parts: main body (1) of the measurement device, lancet (3) mounted in an appropriate position of said main body (1) of the measurement device in a quick connect/disconnect manner, cap body (2) for the lancet to fit on said main body (1) of the measurement device in a quick connect/disconnect manner and covering said lancet (3), and enzyme electrode (4) which is set inside said cap body (2) for the lancet, and which has its connecting terminal connected to connector (14) of said main body (1) of the measurement device.

Said main body (1) of the measurement device is formed as a cylindrical rod-shaped pen body. While not shown in the figure, there is an in-blood component determining means (means for determining the concentration of the in-blood component from the output of the enzyme electrode) contained in it. Also, display unit (11) (a liquid crystal display unit) and operation unit (12) are set at appropriate sites outside it. Also, plunger (13) is set on the back end. In addition, as shown in Figure 3, on the tip side of main body (1) of the measurement device, connecting end (41a) of enzyme electrode (4) to be explained later is inserted, and connector (14) for connecting to the determining means is set.

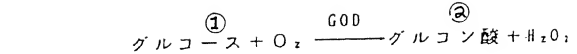
As shown in Figure 3, said lancet (piercing needle) (3) is mounted protruding on the tip portion of main body (1) of the measurement device via holding unit (15) in a quick connect/disconnect manner. Said lancet (3) is connected to said plunger (13) via a back and forth moving means, such as a spring mechanism (not shown in the figure), and by the operation of plunger (13), it can protrude from the tip side of cap body (2) for the lancet to be explained later.

As shown in Figure 2, said cap body (2) for the lancet is a case body fitted on the tip portion of main body (1) of the measurement device in a quick connect/disconnect manner. It is a cylindrical case that also becomes the tip of a micropipette. This cap body (2) for the lancet has both ends opened, with tip side opening (22) as the hole portion for protruding/retreating of said lancet (3). Also, although not shown in the figure, with respect to cylindrical case (cap body) (2) which also acts as the tip of a micropipette, said plunger (13) is set to have the function of feeding and exhausting of blood, reference solution, and cleaning buffer solution. That is, for plunger (13) that is protruded/retreated in two steps, in the first step of the pushing operation, lancet (3) is protruded; then, in the second step of the pushing operation, the reference solution or cleaning buffer solution is fed/exhausted (not shown in the figure).

As shown in Figures 4 and 5, said enzyme electrode (4) is set at an appropriate site on the inner surface of cap body (2) for the lancet. Said enzyme electrode (4) comprises electrode-supporting substrate (41), functional electrode (42), and control electrode (43) (the substrate electrode is formed from these two electrodes (42) and (43)), insulating protective membrane (44), and immobilized enzyme film (45). Said electrode-supporting substrate (41) is a plastic film or other insulating material, and functional electrode (42) and control electrode (43) are formed on said electrode-supporting substrate (41). Said substrate electrode may be formed as a platinum film by means of sputtering, vacuum deposition, ion plating, or another method. Also, the material for the substrate electrode is not limited to platinum. Other forming means may also be adopted, such as bonding of a plating foil, etc. In addition, on said electrode-supporting substrate (41), insulating protective film (44) is formed except for connecting end (41a). Also, functional electrode (42) and control electrode (43) are covered except sensing portions (42b), (43b), and connecting portions (42a), (43a). For insulating protective film (44), a photosensitive

polyimide resin is used, and the sensing portion is defined by means of photolithography. Also, on said insulating protective film (44), immobilized enzyme film (45) is formed. Said immobilized enzyme film (45) has a 3-layer configuration comprising Naphion[transliteration] layer (45a), enzyme layer (45b), and Naphion layer (45c) laminated to each other. Naphion is a commercial name of a product of polyperfluorosulfuric acid manufactured by DuPont Co. of the USA. It is a cationic exchange polymer. The commercially available form of Naphion is a 5% solution (with ethyl alcohol as the solvent). It can easily form a film. In the application example, the film is formed by means of dip coating. Enzyme layer (45b) is prepared by dip coating with an enzyme solution to form a film. The enzyme solution is prepared by adjusting to have 10% of glycose oxidase (GOD), 7.5% of bull serum albumin (BSA), and 0.5% of glutar aldehyde in 0.1 mol of phosphate buffer solution (pH 6.0). Enzyme electrode (4) with said configuration is bonded by an adhesive on the inner peripheral portion of cap body (2) for lancet. In this case, connecting end (41a) is exposed outside cap body (2) for the lancet, and connecting ends (42a) and (43a) of functional electrode (42) and control electrode (43) can be connected to connector (14) of main body (1) of the measurement device (see Figure 3).

When the in-blood component concentration measurement device with the aforementioned configuration is used to measure the concentration of the in-blood component, the operation is performed as follows. Main body (1) of the measurement device with cap body (2) for the lancet mounted on it is pressed so that end surface (2a) of cap body (2) for the lancet comes into close contact with the surface of the finger tip. Then, as the first stage of plunger (13) is pushed in the 2-step operation, lancet (3) protrudes from the tip of cap body (2) (opening hole (22)), and blood comes out from the skin surface. The blood comes into contact with enzyme electrode (4) on the inner surface of cap body (2) for the lancet, so that measurement can be performed. As the blood makes contact with enzyme film (45) of enzyme electrode (4), the following reaction takes place due to the enzyme glucose oxidase (GOD) in enzyme film (45).



Key: 1 Glucose
2 Gluconic acid

In this case, the hydrogen peroxide (H_2O_2) generated is oxidized at sensing portion (42b) of functional electrode (42a), and the oxidation current becomes the electrode output. From the output of the electrode, it is possible to determine the concentration of glucose in the blood from a stoichiometric point of view. Upon completion of the measurement, the second stage of plunger (13) is pushed to exhaust the blood. Due to operation of plunger (13), the cleaning buffer solution is fed and exhausted, and enzyme electrode (4) is cleaned. Also, exchange of lancet (3) is performed as cap body (2) for lancet is removed from main body (1) of the measurement device (see Figure 3).

In the aforementioned application example, as the enzyme GOD is immobilized and the concentration of glucose in the blood is determined. However, it is also possible to determine the concentration of other components other than glucose in the blood by making appropriate changes in the design.

Effect of the invention

In this invention, the aforementioned configuration has the following effects.

① As both the lancet and the enzyme electrode are set together in a single measurement device, it is simple to prepare the measurement, and measurement can be easily performed by operation of the micropipette.

② Also, there is no need to move the finger with blood attached to it. Consequently, it is possible to ensure that the collected blood sample is used in the measurement.

③ As the enzyme electrode is not touched in the wiping-up operation, etc., the enzyme film is not damaged, and the substrate electrode is not scratched.

④ The enzyme electrode has a simple structure and can be manufactured in mass production with a low cost. Consequently, it may be used as a disposable type.

⑤ Exhaustion of the cleaning buffer solution, etc., is carried out by means of the exhaustion operation of the micropipette. Consequently, no residual liquid drop is left on the enzyme electrode. Consequently, it is possible to prevent carry-over, and a high measurement precision can be realized.

⑥ As the enzyme film is integrally covered on the substrate electrode, the adhesion degree between the enzyme film and the substrate electrode is constant, and measurement can be performed with excellent reproducibility.

⑦ Also, as there is no need to exchange the enzyme film, there is no need to perform a wiping of the substrate electrode and other operations that require great care.

⑧ Exchange of the enzyme electrode can be performed by connecting/disconnecting the cap body for the lancet, and the exchange operation is very easy.

⑨ Only small amounts of cleaning buffer solution and reference solution are needed in addition to the blood, there is no need to use a wiping tool, and the operating costs can be cut.

These are excellent effects of the invention.

Brief description of the figures

Figure 1 is an oblique view illustrating the in-blood component concentration measurement device in an application example. Figure 2 is a cross-sectional view of the cap body for the lancet in the in-blood component concentration measurement device of the application example. Figure 3 is an oblique view illustrating the state after the cap body for the lancet of the in-blood component concentration measurement device in the application example is removed. Figure 4 is a longitudinal cross-sectional view illustrating the main portion of the enzyme electrode of the in-blood component concentration measurement device in the application example. Figure 5 is a lateral cross-sectional view illustrating the main portion of the enzyme electrode of the in-blood component concentration measurement device in the application example. Figure 6 is an oblique view illustrating a conventional in-blood component concentration measurement device.

1 Main body of the measurement device

2 Cap body for the lancet

3 Lancet
4 Enzyme electrode
14 Connector
41a Connecting end

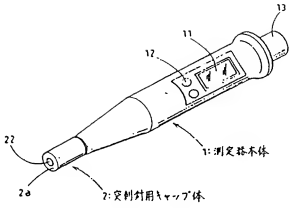


Figure 1

Key: 1 Main body of the measurement device
2 Cap body for the lancet

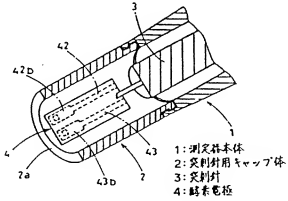


Figure 2

Key: 1 Main body of the measurement device
2 Cap body for the lancet
3 Lancet

4 Enzyme electrode

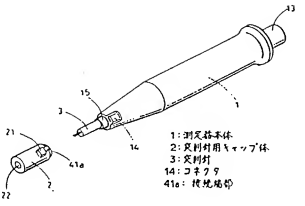


Figure 3

Key: 1 Main body of the measurement device
2 Cap body for the lancet
3 Lancet
14 Connector
41a Connecting end

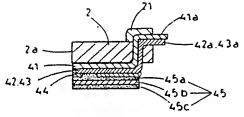


Figure 4

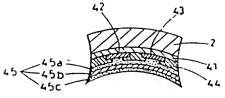


Figure 5

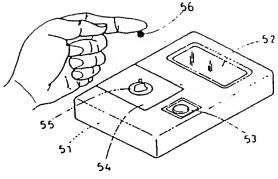


Figure 6